DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October, 22, 2014

Liaoning Upcera Company Limited
C/O Mr. Charles Shen
Manton Business and Technology Services
853 Dorchester LN, Unit-B
New Milford, NJ 07646

Re: K141724
Trade/Device Name: Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: July 24, 2014
Received: July 24, 2014

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number (if known): N/A K141724

Device Name: Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank

Indications for Use:

Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed thought dental laboratories or by dental professionals.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Liaoning Upcera Co., Ltd
No.122 Xianghuai Road, Economic Development Zone, Benxi, Liaoning, China
Tel: (086)-24-45565006
Submitter's FDA Registration Number: 3010582952
www.upcera-dental.com

5.2 Contact Person

Charles Shen
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853 Dorchester LN, Unit-B
New Milford, NJ 08534
Tel: 608-217-9358
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5.3 Date of Summary: June 19, 2014

5.4 Device Name:

Proprietary Name:	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
Common Name:	Dental Zirconia Ceramics
Classification Name:	Powder, Porcelain
Device Classification:	II
Regulation Number:	21 CFR 872.6660
Panel: General	Dental
Product Code:	EIH

5.5 Predicate Device Information:

(1) K093560, "Upcera Zirconia Blanks", manufactured by "Shenyang Upcera Co., Ltd."

5.6 Device Description:

Upcera Dental Zirconia Blanks are derived from Zirconia powder that has been processed into their final net shapes. These blanks are then being further fabricated into all-ceramic restorations such as crowns, bridges, veneers, inlay/ onlay. The zirconia powder is composed of $ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3$ with its composition conforms to ISO 13356,

Implants for Surgery – Ceramic Materials Based on Yttria-Stabilized Tetragonal Zirconia (Y-TZP). The performance of the dental blanks conforms to ISO 6872, *Dentistry: Ceramic Materials*

Upcera Dental Zirconia Pre-Shaded Blanks are derived from the same Zirconia powder as the regular Upcera Dental Zirconia Blanks, with the addition of very small amount of inorganic pigments, before the composite material is processed into their final net shapes. These blanks are then being further fabricated into all-ceramic restorations such as crowns, bridges, veneers, inlay/ onlay. The purpose of the inorganic pigments is to generate the color on the prosthetic dental devices, after sintering at dental labs, that matches natural color of patient's teeth. The performance of the pre-shaded dental zirconia blanks conforms to ISO 6872: 2008, *Dentistry: Ceramic Materials*

5.7 Intended Use:

Upcera Dental Zirconia Blanks & Dental Zirconia Pre-Shaded Blanks are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed thought dental laboratories or by dental professionals.

5.8 Summary of Device Testing:

Bench testing was performed per ISO 6872:2008 and internal procedures to ensure that the Upcera Dental Zirconia Blanks & Dental Zirconia Pre-Shaded Blanks met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

5.9 Technological Comparison with Predicate Device

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, Material, and Processing

Description	Our Device	Predicate Device (K093560)
Indication for Use	Upcera Dental Zirconia Blanks & Dental Zirconia Pre-Shaded Blanks are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed thought dental laboratories or by dental professionals.	Upcera Zirconia Blanks are indicated for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed thought dental laboratories or by dental professionals.
Basic Design	Blocks, disc, and rod	Blocks, disc, and rod
Materials	Regular: Zirconia ($ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3 \geq$ 99.0%)	Zirconia ($ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3 \geq 99.0\%$)

	Pre-Shaded: Zirconia ($ZrO_2 + Y2O_3 + HfO_2 + Al_2O_3 \geq$ 98.0%) Inorganic pigments (Fe_2O_3, Pr_2O_3, and Er_2O_3, <2.0%)	
Processing	Sintering at temperature > 1500 °C	Sintering at temperature > 1500 °C
Dimension	Various	Various
Single Use	Yes	Yes
Color	None, and Pre-shaded (for pre-shaded series)	None
Sterile	Non-sterile	Non-sterile

Our device is essentially identical to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate devices. The only minor difference is that the predicate device has no color, while our devices in submission have both the non-color regular series and pre-shaded series of twenty one different colors. The colors are originated from inorganic pigments of Fe_2O_3, Pr_2O_3, and Er_2O_3, that are of very small amount (< 2.0%), and does not raise any safety issues, demonstrated by biocompatibity study.

5.10 Comparison of Performance with Predicate Device

Performance testing was performed on the subject device and results were compared with predicate device. Tests were conducted following applicable procedures outlined in the FDA recognized consensus standard of ISO 6872, and results met all relevant requirements in the test standard. Test results on radioactivity, pre-sintered density, sintered density, and flexural strength of the subject device are very similar to the predicate device.

The following table shows similarities and differences of the biocompatibility between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the FDA recognized consensus standard of ISO 10993, and results met all relevant requirements in the test standards, and are comparable to the predicate device.

Table 5.2: Comparison of Biocompatibility Testing

Description	Our Device[a]	Predicate Device (K093560)
Cytotoxicity (ISO 10993-5:2009)	No cyteotoxicity effect	No cyteotoxicity effect
Irritation Oral Mucosa	Not a primary oral mucosa	No intracutaneous reactivity

Irritation (ISO 10993-10: 2010)	irritant under the conditions of the study	
Sensitization (ISO 10993-10: 2010)	Not a sensitizer under the conditions of the study	Not a sensitizer under the conditions of the study
Subacute and Subchronic Toxicity (ISO 10993-11: 2006)	No subacute and subchronic toxic effects observed	No acute toxicity
Genotoxicity (ISO 10993-3: 2003)	No genotoxic effects observed	N/A

[a]: Performed on pre-shaded zirconia blanks to cover both the regular and pre-shaded zirconia blanks.

Therefore, Upcera Dental Zirconia Blanks & Dental Zirconia Pre-Shaded Blanks manufactured by "Liaoning Upcera Co., Ltd." meet requirements per ISO 6872 and ISO 10993-1. It is safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses. The test results are also comparable to the predicate device.

5.11 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank and its predicate devices have the identical indications for use, similar composition and biocompatibility, similar manufacturing process, and similar performance.

The difference between the Upcera Dental Zirconia Blanks & Dental Zirconia Pre-Shaded Blanks and their predicate device do not raise any question regarding its safety and effectiveness.

Upcera Dental Zirconia Blanks & Dental Zirconia Pre-Shaded Blanks, as designed and manufactured, are as safe and effective as its predicate device, and therefore is substantially equivalent as its predicate device.